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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/075,429	Applicant(s) MARTANI, ROSA
	Examiner Susan Tran	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Preliminary Amendment filed 02/13/02, and Information Disclosure Statement filed 04/01/02.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 12-26 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-15 of prior U.S. Patent No. 6,083,531. This is a double patenting rejection.

Non-statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-19 of U.S. Patent No. 6,083,531. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the application and patent are claiming the same end result, e.g., rapidly dissolving oral dosage form having density of 200-1000 mg/ml, which dissolves within 15 seconds.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 are indefinite because step (d) is confusing. Step (d) recites "putting the compacted powder or granulate so obtained on the top of the liquid which according to (b)(1) or (b)(2)". However, neither (b)(1), (b)(2), nor (c) recites "compacted powder or granulate so *obtained on the top of the liquid*". It is suggested to rephrase step (d), or further clarification is requested.

Regarding claims 1-3, 15-17, and 19-21, the phrase "other ingredients" or "other usual pharmaceutically excipients" renders the claim indefinite because it is unclear whether the "other" limitations are part of the claimed invention.

Claims 4 and 8 are indefinite in the use of the phrase "selected from". If Markush language is intended, the appropriate phrasing is "selected from the group selecting of" group I, II, *and* III.

Claim 8 is rejected in the use of the phrase "at least two different techniques". However, it appears that there are at least three different techniques recite in claim 8, that are "forced warm gas, microwave radiation, and reduced pressure". Further clarification is suggested.

Claim 10 recites the limitation "solid pharmaceutical or veterinary dosage form" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. The limitation "solid pharmaceutical or veterinary dosage form" has not been introduced in claim 1.

Claims 13-26 recite the limitation "pharmaceutical or veterinary solid dosage form" in lines 1-2. There is insufficient antecedent basis for this limitation in the claims. The limitation "pharmaceutical or veterinary" has not been introduced in claim 12.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claims 12-26 are directed to the same invention as that of claims 1-15 of commonly assigned US 6,083,531. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

Claims 12-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Humbert-Droz et al. WO 97/38679.

Humbert-Droz teaches fast disintegrating oral dosage form comprising active agent, filler, binding agent (disintegration agent), and talc as lubricant pages 3-4, and claims 1-13. The dosage form can be a tablet, which disintegrate in the mouth within 15

seconds, and have a density of 200-1000 mg/ml (pages 5-6). The dosage form is prepared without applying any freeze-drying, or any compression force (page 5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Humbert-Droz et al.

Humbert-Droz teaches process for preparing fast disintegrating oral dosage form discloses in pages 5-6. It appears that Humbert-Droz is silent as to the teaching of compacting a suitable amount of the prepared powder or granulate as claimed in step (c). However, it is the position of the examiner that no criticality is seen in the particular step, since the prior art obtains the same result desire by the applicant, e.g., fast disintegrating oral dosage. Although, Humbert-Droz does not teach compacting the prepared powder or granulate, the extra step does not impart patentability over the applied prior art. Applicant's desire to produce rapidly dissolving dosage form, Humbert-Droz produces rapidly dissolving oral dosage form. Thus, it would have been prima facie obvious for one of ordinary skill in the art to, by routine experimentation modify Humbert-Droz with the expectation of similar result, because Humbert-Droz

teaches a rapidly dissolving oral dosage form having the same density and the same disintegrating time.

Claims 12-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Humbert-Droz et al.

Humbert-Droz is relied upon for the reasons stated above. In the case that the applicant can overcome the above 102(b) rejection, the examiner relies on the following 103(a) rejection. One of ordinary skill in the art would have been motivated to modify Humbert-Droz's composition to obtain the claimed invention because Humbert-Droz teaches a rapidly dissolving oral dosage form having the claimed density of 200-1000 mg/ml, and disintegrating time of within 15 seconds (pages 2-5).

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Geyer et al., Ohno et al., and Masaki et al. are cited as being of interest for the teachings of solid pharmaceutical prepartion.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

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